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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,259	09/12/2003	Ben-Zon Dolitzky	1662/568077	7774

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary
for Applications
Under Accelerated Examination**

Application No.

10/661,259

Applicant(s)

DOLITZKY ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Since this application has been granted special status under the accelerated examination program,
**NO extensions of time under 37 CFR 1.136(a) will be permitted and a SHORTENED STATUTORY PERIOD FOR
REPLY IS SET TO EXPIRE:**

ONE MONTH OR THIRTY (30) DAYS, WHICHEVER IS LONGER,
FROM THE MAILING DATE OF THIS COMMUNICATION – if this is a non-final action or a *Quayle* action.
(Examiner: For **FINAL** actions, please use PTOL-326.)

The objective of the accelerated examination program is to complete the examination of an application within twelve months from the filing date of the application. Any reply must be filed electronically via EFS-Web so that the papers will be expeditiously processed and considered. If the reply is not filed electronically via EFS-Web, the final disposition of the application may occur later than twelve months from the filing of the application.

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2006.
2) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 3) ☒ Claim(s) 1-10, 121 and 123-130 is/are pending in the application.
3a) Of the above claim(s) _____ is/are withdrawn from consideration.
4) ☐ Claim(s) _____ is/are allowed.
5) ☒ Claim(s) 1-10, 121, 123-130 is/are rejected.
6) ☐ Claim(s) _____ is/are objected to.
7) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 8) ☐ The specification is objected to by the Examiner.
9) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
10) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 11) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment and response filed by applicants dated Jun 19, 2006 have been entered and considered carefully.

Claims 11-120, 122, 131 have been canceled. Claims 1-10, 121, 123-130 are pending.

2. Applicants have amended claim 6 to incorporate the step of "trituration". The 102(a) rejection of claims 6-9 is dropped and replaced with the 103(a) rejection as following:

Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al.

WO 00/71124 in view of Hackh's Liberman, Sekiguchi or Leucuta.

Determination of the scope and content of the prior art (MPEP §2141.01)

Kumar et al. '124 disclosed process for preparation of amorphous fexofenadine hydrochloride which anticipated the basic steps of the claims see examples 1-5.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between Kumar et al. and the instant claims is that an trituration step was added after preparation of amorphous form, a trituration step was carried out. Hackh's chemical dictionary defined that trituration is a grinding of particles or a size reduction procedure. Sekiguchi disclosed advantages of wet milling suitable for pharmaceuticals for size reduction. Liberman taught that size reduction in pharmaceuticals is desirable since the smaller particle size will have formulation advantages (see p.110-111) and such effect has been evidenced in pharmaceutical products (see Leucuta).

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would be aware of all the relevant art in the pharmaceutical size reduction and formulation field. The above reference placed the motivation of size reduction, the reasonable success of size reduction by trituration, and the expected advantage in formulation in the possession of one having ordinary skill in the art. The addition of a conventional size reduction step in a proven process is prima facie obvious.

3. The rejection of claims 1-10, 121, 123-130 under 35 USC 103(a) over Kumar in view of Okabe or Williams or over Carr, '129, '437, Woosley '693 in view of Lieverman, Suzuki, Corrigan, Nuernberg, Sato supplemented with '127 are maintained for reason of record.

The gist of applicants' arguments with respect to the 103(a) rejection are:

(i) there are other steps in the claim, therefore, the sole difference between the claims and the prior art is not spray drying vs evaporation.

Please note that the other steps in claim 1 is "preparing a solution, removing a portion of the solvent, adding another solvent, when two layer forms, separate the two layers".

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This adding one solvent, adding another immiscible solvent so that two layer forms to separate the lower layer is clearly known conventionally in the chemical art as “extraction” process. Please note that whether the fexofenadine hydrochloride was dissolved in one solvent or extracted into another solvent, such steps are the preparation step of solution making conventional in the chemical art. The Kumar ‘124 reference on pages 4-5 delineated preparation of solution. The Williams ‘890 reference taught that spray drying is solvent removal procedure analogous to other conventional solvent removing procedures (see col. 1, lines 26-27, col. 2 lines 59-60) and particularly taught the equivalency between applicants tetrahydrofuran and other alcohols such as those used by Kumar ‘124. Okabe et al. is further evidence that such analogue between spray drying and evaporation is a broad spectrum approach per ponderously conventional in the industry in amorphous solid preparation.

Attorney’s attempt to show unobviousness by comparing only the difference of *each individual* reference instead of the combination of well-known analogous art in the field does not warrant any probative value. In re Merck & Co. 231 USPQ 375, Ex parte GPAC Inc. 29 USPQ2d 1406. Please note both Kumar and Williams have particularly “named” applicants compound and the all three references are for “solid amorphous” product procedure, thus, all are analogous art. Although the Okabe reference was recited as an example of the well known nature between spray drying and *rotary* drying, per ponderous of evidence in the pharmaceutical art support the analogue, see for example CA 139:219273, CA 113:120830, CA 138:390718, CA 141:179642, which are just a brief browsing of the most recent publication.

Applicants further argued that newly amended step in claims 6 and 125 of “trituration” which also differ from the prior art. On page 9 of the specification, it has clearly disclosed that trituration is an optional step further made “after” an amorphous form was received. The addition of an conventional size reduction step may obviate anticipation but does not obviate the obviousness see supra new ground of rejection necessitated by applicants amendment.

(ii) polymorphism is unpredictable. Please note that any unpredictability in the field of polymorphism has absolutely no relevancy on the instant claims which are amorphous products. The Wikipedia encyclopedia is hereby attached for applicant’s convenience. Please note that the definition of polymorphism strictly is for “crystal structure”. Amorphous is not crystal. Any unpredictability in crystal structure has no relevancy on amorphous because they are predictable and stable as Lieberman of record has taught. Even if there are unpredictable factors in obtaining “multiple” crystalline forms for a known crystal, the encyclopedia clearly provided evidence that just because there are many factors to be considered thus is time consuming, such process of multiple crystalline form is not unpredictable but proportional to the time and money one is willing to spend on such project.

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4. The provisional rejection of claims 1-10, 121, 123-130 under 35 USC 102(e) or (g) over US 2005/0165056 is maintained for reason of record.

In response to the 102(e) or (g) rejection, applicants argued that such “in this country” situation is not likely. It is a *provisional* rejection and decisions can only be made when the allowable scope of the instant claims were found and the priority benefit of the specific allowable scope be compared at that time.

5. Applicants amendment necessitated the new grounds of rejection.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Aug. 31, 2006

A handwritten signature in black ink, appearing to read 'Celia Chang', with a stylized, cursive script.

Celia Chang
Primary Examiner
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